

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

**In re: PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE LITIGATION**

)
) **MDL No. 1456**
) **Master File No. 01- 12257-PBS**
) **Subcategory Case. No. 06-11337**
)

THIS DOCUMENT RELATES TO:

) **Hon. Patti B. Saris**
)

*United States of America ex rel. Ven-A-Care of the
Florida Keys, Inc., et al. v. Dey, Inc., et al.,*
Civil Action No. 05-11084-PBS

) **Magistrate Judge**
) **Marianne B. Bowler**
)
)

**DEY'S OPPOSITION TO PLAINTIFFS' MOTION IN LIMINE
TO EXCLUDE CERTAIN TESTIMONY OF DR. LAUREN J. STIROH**

Defendants Dey Pharma, L.P. (formerly known as Dey, L.P.), Dey, Inc., and Dey L.P., Inc. (collectively "Dey") hereby submit their opposition to the Plaintiffs' Motion in Limine to Exclude Certain Testimony of Dr. Lauren J. Stiroh (Dkt. 7125).

INTRODUCTION

Based on a reading of Plaintiffs' motion alone, one would be under the impression that Dr. Stiroh has offered limited opinions on the industry practice of the pharmaceutical industry, has opined as to the "accuracy" of Dey's WAC, and has speculated as to the actions of Medicare and Medicaid. However, an examination of the entirety of Dr. Stiroh's report paints the accurate picture of the actual, complex, economic opinions offered by Dr. Stiroh. Plaintiffs have only challenged five of the numerous opinions set forth in Dr. Stiroh's expert report and rebuttal report, and have mischaracterized these cherry-picked opinions in their Memorandum of Law, Dkt. 7126 ("Plaintiffs' Memo"). Plaintiffs have also glossed over the basic fundamentals underlying Dr. Stiroh's opinions which provide the necessary context and background for those

five opinions. When examined in the context of Dr. Stiroh's reports, the relevancy and reliability of Dr. Stiroh's opinions is evident.

Dr. Stiroh is an economist and Senior Vice President of NERA Economic Consulting. Dr. Stiroh received her B.A. in economics from the University of Western Ontario in 1990, her M.A. from the University of British Columbia in 1991, and her Ph.D. from Harvard University in 1996. Dr. Stiroh has provided economic consulting services and testimony in a number of damages cases and has testified at trial and in depositions regarding a variety of business practices, including commercial disputes, business interference, breach of contract, allegations of monopolization, price predation, unlawful tie-ins, price discrimination, abuse of market power, and patent infringement. Dr. Stiroh has experience with damages issues in a number of industries including pharmaceuticals, biotechnology, medical devices, advertising and promotion, consumer products, agricultural products, industrial chemicals, and semiconductors.

As an economist, Dr. Stiroh looks for evidence of market behavior. In this case, she used her expertise to examine how the pharmaceutical market functioned beginning in the early 1990s to the present. Dr. Stiroh examined the various pricing points that are available in the pharmaceutical market, including Dey's reported AWP, Dey's reported, declining WACs, the AMPs which Dey reported to CMS on a quarterly basis, the FSS prices that the federal government negotiated directly with Dey, and the IMS data which was available in the industry. In connection with her assessment of the market, Dr. Stiroh also reviewed documents and depositions that are a part of the factual record in this case. She noted that AWP was not defined by Medicaid or Medicare regulation, unlike the case of AMP, WAC as of 2003, or ASP as of 2003.¹ Dr. Stiroh then looked to Dey's transactional data to see how Dey acted as a participant

¹ The First Circuit in its opinion issued after Dr. Stiroh submitted her reports noted in the context of the history set forth in the MDL consumer fraud case that the "precise meaning of AWP" was "unsettled"; and even this

in this established market during the period from 1991 through 2008. She examined Dey's voluminous sales transaction data for the drugs at issue in this case and the relationship of the other pricing points in the market to determine, from an economic perspective, if Dey's behavior was consistent with that of a rational economic actor.

With this background, Dr. Stiroh addresses several questions in her report, including: (1) Given the market and available pricing in the market, what was Dey's economic state of mind?; and (2) Have Plaintiffs set forth a viable damage model in this case? Dr. Stiroh's opinions that are set forth in her report and rebuttal report are her answers to these questions.

I. DR. STIROH'S OPINIONS ARE PROPERLY EVALUATED IN THE CONTEXT OF TRIAL, ESPECIALLY BECAUSE IT IS NOT CLEAR THAT SHE WILL TESTIFY

As an initial matter, the Plaintiffs' piecemeal motion is premature and asks the Court to attempt to parse opinions which need to be heard in a trial context. In a *Daubert* challenge, the role of the Court is as the gatekeeper:

we emphasize that the court's gatekeeping function focuses on an examination of the expert's methodology. The soundness of the factual underpinnings of the expert's analysis and the correctness of the expert's conclusions based on that analysis are factual matters to be determined by the trier of fact, or, where appropriate, on summary judgment. *See Daubert*, 509 U.S. at 595, 113 S.Ct. 2786 ("The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate."); *Walker*, 208 F.3d at 587 (stating that when addressing whether expert testimony is reliable the district court should not consider the "factual underpinnings" of the testimony but should determine whether "it was appropriate for [the expert] to rely on the test that he administered and upon the sources of information which he employed").

Court found that on that MDL record "by 2003, the term 'average wholesale price' had become a term of art, finding that by that point 'Congress clearly did understand AWP was different than average sales price and was not reflective of actual prices in the marketplace.'" *In re Pharm. Indus. Average Wholesale Price Litig.*, 582 F.3d 156, 168-170 (1st Cir. 2009).

Smith v. Ford Motor Co., 215 F.3d 713, 718 (7th Cir. 2000) (reversing exclusion of expert witnesses and remanding for new trial). Here, however, the Plaintiffs have improperly asked the Court to evaluate the factual underpinnings of selected parts of Dr. Stiroh's analyses and the correctness of several of her conclusions on issues such as dispensing fees. These types of issues, even if shaky, which Dr. Stiroh's are not, are properly left for cross-examination.

"Exclusion of expert testimony is the exception rather than the rule because vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence."

McGonigal v. Sears Roebuck & Co., Civil Action No. 07-CV-4115, 2009 WL 712345, at *5 (E.D. Pa. Mar. 13, 2009) (internal citations omitted); *see also Taylor, Bean & Whitaker*

Mortgage Corp. v. GMAC Mortgage Corp., No. 5:05-cv-260-Oc-GRJ, 2008 WL 3819752, at *5 (M.D. Fl. Aug. 12, 2008).

Furthermore, it is in the interests of judicial economy for the Court to refrain from ruling on Plaintiffs' motion until the time Dr. Stiroh is to testify. Plaintiffs have challenged five of the numerous opinions set forth in Dr. Stiroh's expert report and rebuttal report. Dr. Stiroh is listed as a may call witness, and at this time, it is not yet clear that Dr. Stiroh will be called to testify at trial, let alone present any of the specific opinions challenged by Plaintiffs in their motion.

Therefore, Dey respectfully requests that the Court defer ruling on the Plaintiffs' motion until such time Dr. Stiroh is to offer her opinions, if at all.²

² During their Local Rule 7.1 conference, Dey suggested arrangement by which the Plaintiffs would reserve the right to challenge any selected opinions of Dr. Stiroh at the time of trial as well as other alternative arrangements. The Plaintiffs preferred to file their motion at this time, however.

II. DR. STIROH'S CRITIQUES OF PLAINTIFFS' EXPERTS' DAMAGE MODEL ARE ADMISSIBLE

Plaintiffs challenge Dr. Stiroh's critique of Plaintiffs' experts' opinions, claiming her critiques are speculative and irrelevant (Plaintiffs' Memo at 12-16), and echoing the arguments made in United States' Motion to Exclude Certain Opinions of W. David Bradford, Ph.D., Dkt. 6193 (the "Bradford Motion"). Dr. Stiroh, in her role as an economist, analyzed the available record and evidence and independently came to many of the same conclusions as Dr. Bradford. As discussed in Dey's briefing on the Bradford Motion, and as discussed in relationship to Dr. Stiroh below, these types of opinions are admissible.³

Through her analysis of the relevant market, Dr. Stiroh found evidence that lower price points were known and available to CMS and the states throughout the relevant time period while Medicare and Medicaid continued to base reimbursement on published prices. As an economist, the availability of known alternatives that are not used in a marketplace is a signal that there is another factor at work in the relevant market. For example, the fact that state Medicaid agencies continue to use AWP in their reimbursement formulas to this day indicates that despite massive litigation and attention to the role of AWP, those state agencies continue to have independent reasons to use AWP as a part of their formula. What Dr. Stiroh's and Dr. Bradford's analyses show is that an allegation of overpayment cannot be presented to the jury without corresponding evidence of all of the elements of payment, including the dispensing fee. An appropriate damage model in this case needs to consider all factors, not just ingredient cost. Dr. Stiroh reaches several opinions about the reliability of Plaintiffs' experts' reports, including the opinion that Plaintiffs' experts:

³ Dey incorporates its response to Plaintiffs' arguments regarding dispensing fee shortfalls in its opposition to the Bradford Motion, Dkt. 6985, as well as its sur-reply memorandum of law, Dkt. 7102, and so will not repeat those arguments here.

do nothing to demonstrate that such a change in reimbursement would have either 1) covered dispensing costs, 2) been successful at ensuring pharmacy participation, or 3) been acceptable to state Medicaid agencies, CMS, or Congress as a measure of reimbursement. They do not consider the implications of their suggested changes to Dey's reporting practices on its overall business and competitive interactions with other market participants. None of plaintiffs' experts properly take account of evidence showing that dispensing fees have increased when ingredient cost reimbursement was decreased or that access is a goal of the Medicare and Medicaid program. Without a cogent and complete theory of how CMS might have changed its reimbursement formulas, including its dispensing fees, had pharmaceutical companies reported average discounted transaction prices in place of AWP, plaintiffs' experts have not shown that there has been any competitive impact from the types of pricing behaviors that have openly existed for more than two decades.

(Stiroh Report at 34).⁴ Dr. Stiroh further opines about this major flaw in methodology as follows:

Dr. Duggan asserts that the empirical methods that he used "for calculating the payment amounts that the Medicaid and Medicare programs would have made are consistent with those that [he] and other economists typically use in academic research." I disagree. Dr. Duggan fails to use any empirical methods typically employed by economists in performing counterfactual analyses, such as the type he purports to have performed here. Properly performed, counterfactual analyses must take into account how all market participants would have behaved under circumstances different from (counter to) the actual market circumstances. Dr. Duggan has not done so. Thus, his report fails to provide any estimate that could properly be considered 'damages.' (*Id.* at 44).

Dr. Stiroh's critique goes to the heart of the Plaintiffs' damage model: namely, that Dr. Duggan and Plaintiffs' other experts have constructed a "but for world" that fails to take into account all of the relevant factors necessary for a true economic analysis. Dr. Duggan changes the AWP and WACs of Dey's products, but neither he nor any of the Plaintiffs' experts

⁴ Dr. Stiroh's March 6, 2009 expert report is attached to Plaintiffs' Memo as Exhibit A and is referred to herein as "Stiroh Report".

examine the other costs inherent in the prescription drug market: dispensing costs. This failure is the equivalent of a damage estimate which holds the quantity of a good constant as prices increase or a model which assumes that market participants would stay the same if barriers to market entry were lifted. Here, through their motions to exclude testimony of Dr. Stiroh and Dr. Bradford, Plaintiffs essentially have asked the Court to pretend that dispensing costs, access, and other considerations other than ingredient cost do not play a role in setting Medicare or Medicaid reimbursement. Meanwhile, Plaintiffs defend the opinions of their experts who failed to examine the key components of access and dispensing costs. The position taken by Plaintiffs and their experts is in direct conflict with the factual record and with the two economists that have reviewed Dr. Duggan's calculations for Dey.⁵

Plaintiffs argue that it is Dey's burden to quantitatively present the evidence. In doing so, they rely on *Ward v. Dixie Nat'l Life Ins. Co.*, 595 F.3d 164 (4th Cir. 2010), which is misplaced as that case does not even involve a *Daubert* motion nor does it stand for the bold proposition that it is Dey's burden to set forth Plaintiffs' relevant damage model. Nonetheless, Dey has met any alleged burden through the extensive evidence presented by Dr. Bradford, which is independently corroborated by Dr. Stiroh's opinions regarding the flaws of Plaintiffs' damage models. Furthermore, courts have held that in the context of trebled damages, plaintiffs cannot assume favorable aspects of the market which would serve to inflate and overestimate already high damage figures. *See, e.g., Toscano v. PGA Tour, Inc.*, 201 F. Supp. 2d 1106, 1125 (E.D. Cal. 2002) (internal citation omitted). While *Toscano* is an antitrust case, the principle is equally

⁵ Medicare must reimburse its providers enough to maintain access for its beneficiaries, and CMS was concerned about access to care. (Neimann 11/19/09 Dep., Exhibit 2 to Dkt. 6986 at 604:10-14). For a more in-depth discussion of the factual record regarding access to care, Dey respectfully refers the Court to its Sur-reply in opposition to Plaintiffs' Motion to Exclude Certain Opinions of David Bradford, Dkt. 7102 at 4-5, which is incorporated herein.

applicable here. Plaintiffs cannot assume, to their favor, that dispensing fees would have stayed the same, when the available evidence shows that they in fact would have increased. As set forth by Dr. Stiroh in her report, the economic damage model used by Plaintiffs “fails to provide any estimate that could properly be considered ‘damages.’” (Stiroh Report at 44).

Plaintiffs also reargue the point made in the Bradford Motion, namely, that Dr. Stiroh’s opinions relating to dispensing fees are speculative. Plaintiffs argue that these opinions are based on studies and evidence that are outside the relevant time period. However, as the Court has commented, Dr. Stiroh is using these figures and evidence as a proxy. This is not improper under any *Daubert* standard. It should be noted that while Dr. Duggan has not calculated damages past Q4 2003, the Amended Complaint sets forth the relevant time period as “[f]rom on or before December 31, 1992, and continuing through 2004 in the case of the Medicare program”. See Dkt. 5614 at paragraph 50 (emphasis added). Therefore, the Plaintiffs’ complaints about the 2004 dispensing cost studies are misplaced, as 2004 is a part of the “relevant” time period under their pleading. Furthermore, Dr. Stiroh’s opinions resulting from her analysis of what actually happened as a result of the studies and evidence regarding the MMA’s dispensing fee changes are not speculative: it is reality. With the enactment of the MMA, Congress lowered ingredient cost reimbursement to 106% of ASP, and in doing so, acted comparably to Dr. Duggan who, in calculating his differences, lowers ingredient cost reimbursement to his calculated average price. However, at the same time, Congress dramatically increased the dispensing fees for Dey’s inhalation drugs, ultimately using a dispensing fee of \$33 where it remains to this day. Dr. Duggan does not change the dispensing fee in his analysis, but rather holds it constant at \$5. Dr. Stiroh disagrees with Dr. Duggan’s damages analysis. Dr. Stiroh correctly uses these studies and the factual record which show

what actually happened when a system similar to that proposed by Dr. Duggan was implemented. The Plaintiffs' disagreement with Dr. Stiroh's ultimate conclusions is not a basis for a *Daubert* motion. Plaintiffs, if they prevail, have the burden of showing the actual overcharges through a valid damage model: by seeking to remove the dispensing cost issue from trial, they are actually seeking a windfall recovery of more than actual overcharges which would then be trebled. Therefore, it is critical that the jury hear Dey's experts' critiques of Plaintiffs' incomplete damages model.

III. DR. STIROH'S OPINIONS ABOUT DEY'S ROLE IN THE MARKET ARE ADMISSIBLE

Plaintiffs challenge several of Dr. Stiroh's opinions that relate to Dey's role as an economically rational participant in the pharmaceutical market. As discussed in more depth below, these opinions are admissible.

A. DR. STIROH'S OPINIONS ABOUT DEY'S SCIENTER ARE ADMISSIBLE

Plaintiffs isolate Dr. Stiroh's conclusions from their analysis in an attempt to discredit them. (Plaintiffs' Memo at 8). Dr. Stiroh's opinions about Dey's economic state of mind result from her economic interpretation of the evidence and transactional data in this case. Dr. Stiroh describes her overall assignment as follows: "[i]n particular, I have been asked to evaluate the plaintiffs' theory considering the economic realities of the pharmaceutical industry and Dey's conduct as a participant in this industry." (Stiroh Report at 1). During her deposition, Dr. Stiroh explained these opinions as follows:

Q. Why did you feel it significant to express your opinions about what Dey believed or what Dey had reason to believe?

A. My opinion is not on what Dey believed. My opinions, as summarized in the -- starting on page 3 -- have to do with whether it is economically rational or reasonable, given the full information available in the market, for a Dey to think that its prices either have

or do not have an impact on Medicaid and Medicare reimbursement, whether there is a reasonable basis for them to believe that Medicare and Medicaid were not deceived by its pricing practices, and whether there is an economic reason for Dey to have believed that Medicaid and Medicare reimbursement amounts were inflated or not inflated as a result of their pricing practices.

(Stiroh May 12, 2009 Dep., Reid Decl. Ex. 1 at 157:1-18). Plaintiffs' only challenge to these opinions, relevancy, is misplaced. Dr. Stiroh's opinion that:

in providing the AMPs, Medicare ASPs, and other price information requested in the negotiation of FSS, it would be economically irrational for Dey to have believed it would have been able to deceive the government that AWP's were transaction prices and that its WACs were anything other than undiscounted invoice prices.

(Stiroh Report at 24), as well as her opinions that as an economically rational actor, Dey had no reason to believe it was deceiving the Government, bear directly on Dey's scienter. Plaintiffs argue that since no proof of specific intent to defraud is required under the False Claims Act, Dr. Stiroh's opinions about Dey's economic state of mind are therefore irrelevant. However, the use of the word "deceive" does not render Dr. Stiroh's opinions irrelevant, when they reach the very relevant issue of whether Dey knew (or was reckless in not knowing) that published AWP's were supposed to reflect acquisition costs through the relevant time frame. *See, e.g., United States ex rel. Farmer v. City of Houston*, 523 F.3d 333, 338 (5th Cir. 2008) ("[The] *mens rea* requirement [of the FCA] is not met by mere negligence or even gross negligence."); *see also United States ex rel. K&R Ltd. P'ship v. Mass. Housing Fin. Agency*, 530 F.3d 980, 983-84 (D.C. Cir. 2008). Dr. Stiroh's opinions about the economic rationality of Dey's state of mind have a direct bearing on the scienter or knowledge element of the False Claims Act.

Dr. Stiroh's opinions relate to whether Dey's reporting of AWP is the action of an objectively rational economic actor. As noted by Dr. Stiroh, "[t]o date, AWP has not been

defined in any statute. In its 2005 report, the Office of Inspector General (‘OIG’) stated that the ‘AWP is not defined in law or regulation, and fails to account for the discounts available to payers.’” (Stiroh Report, at 18). In this context, Dr. Stiroh opines that Dey’s actions were objectively reasonable. As the Supreme Court explained, where a defendant’s reading of a statute, contract, or regulation is “objectively reasonable,” it lacks scienter, *see Safeco Ins. Co. of Am. v. Burr*, 551 U.S. 47, 69-70 & n.20 (2007), and that applies equally to the FCA. Plaintiffs themselves admit that the question of “whether Dey knew that its reported prices were false” is relevant. (Plaintiffs’ Memo at 10). The FCA’s scienter requirements therefore necessitate consideration of whether Dey’s understanding is unreasonable. Dr. Stiroh’s opinions about the information and other prices available in the marketplace during the relevant time frame demonstrate that Dey’s actions were not “objectively unreasonable” given the “dearth of guidance and the less-than-pellucid statutory text”: “This is not a case in which the business subject to the Act had the benefit of guidance from the courts of appeals . . . that might have warned it away from the view it took.” *Safeco*, 551 U.S. at 70.

Plaintiffs also argue that Dr. Stiroh’s reference to the availability of other information in the marketplace is irrelevant. Dr. Stiroh’s opinions are directly relevant to key elements of the False Claims Act claims against Dey. In the absence of any regulatory guidance from the Government, in addition to Dey’s disclosures, Dey publicly reported its declining WACs, provided its AMPs directly to CMS, and negotiated FSS prices directly with the Government. Dey also disclosed its understanding of AWP and made clear to Medicaid and Medicare that its AWP did not reflect actual transaction prices. Thus, as far as Dey was concerned, as a rational economic actor in the marketplace, it was not reporting “false” prices to the compendia.

B. DR. STIROH'S OPINIONS ON DEY'S UNDERSTANDING OF INDUSTRY PRACTICE ARE ADMISSIBLE

Plaintiffs mischaracterize Dr. Stiroh's opinion about industry practice in a transparent, and unsuccessful, effort to undermine her expertise. The phrase "industry practice" appears three times in the text of Dr. Stiroh's report, and nowhere in her reports, the official record of her opinions, does she opine that there was there an industry practice among generic drug manufacturers in setting AWP. Dr. Stiroh opines that "Dey's practice [of setting its AWP] is consistent with *its* understanding that industry practice was generally to 'set' AWP at about 90 percent of the brand AWP for launch and generally not update it over time." (Stiroh Report at 16) (emphasis added). When asked about this opinion at her deposition, Dr. Stiroh explained that the context of her understanding was how Dey used its AWP:

Q. What is the context in which Dey uses AWP?

A. As a signal at launch that it has a generic pharmaceutical product that is generic to a brand and is eligible to be substituted for the brand under generic substitution laws.

Q. What understanding do you have of what a company needs to do in order to give that signal at launch?

A. My understanding is that a company of -- generic pharmaceutical manufacturer has to have a pharmaceutical product that is approved by the FDA, that it has to be the same dosage, strength, route of administration as the brand to which it is generic, and that the signal that the product that is a generic and available for distribution to end patients comes from a published AWP at launch that is below the brand AWP.

Q. Any amount below?

A. My understanding, there is essentially an industry practice that it is 10 to 20 percent below the AWP.

Q. Where does that understanding come from?

A. As it applies to this case, from deposition testimony in connection with this case.

(Stiroh May 12, 2009 Dep., Reid Decl. Ex. 1 at 46:19-48:2). The other two mentions of “industry practice” in Dr. Stiroh’s reports also relate to Dey’s understanding of the industry practice, and reference the price notification letters Dey sent to Medicaid and Medicare agencies in which Dey describes its AWP as follows:

Further, as you also know, the Average Wholesale Price (or ‘AWP’) per unit listed above does not represent actual wholesale prices which will be charged or paid for this product. It is Dey’s practice to set an AWP before a product is first sold and not subsequently to change that figure. We understand that this is consistent with industry practice and is understood by state and federal Medicaid regulators.

(Stiroh Report at 22).

It appears that Plaintiffs’ critique of Dr. Stiroh’s supposed “industry practice” opinion is based on their misinterpretation of Dr. Stiroh’s expert report. Dr. Stiroh does not opine that there is a standard industry practice. Dr. Stiroh’s opinion relates to Dey’s understanding of industry practice and her examination of Dey documents and testimony fit with her opinion and renders her opinion more, and not less, reliable.

Dr. Stiroh formed her opinions regarding Dey’s understanding of industry practice as set forth in her report after her extensive analysis of Dey’s transactional data as well as the testimony and other documentary evidence that is a part of the factual record. Her evaluation of Dey’s understanding of the purpose of AWP is a key to her overall task of evaluating “the plaintiffs’ theory considering the economic realities of the pharmaceutical industry and Dey’s conduct as a participant in this industry.” (Stiroh Report at 1). Therefore, this opinion fits squarely within her expertise, as she is an economist with the training and expertise needed to review and analyze this record.⁶ Such an opinion is reliable and admissible.

⁶ Furthermore, Dr. Stiroh’s opinion that “Dey’s practice [of setting its AWP] is consistent with *its* understanding that industry practice was to generally ‘set’ AWP at about 90 percent of the brand AWP for launch

Furthermore, Dr. Stiroh's analysis of the record and subsequent opinions do not equate to the self-serving statements acknowledged by the court in *Lang v. Kohl's Food Stores, Inc.*, 217 F.3d 919, 923-24 (7th Cir. 2000). In that employment discrimination case, the court critiqued the fact that the expert had prepared a supplemental report based solely on his focus group discussion with certain members of the class plaintiffs. However, in that case, the court's main reason for exclusion was because the expert had provided absolutely no explanation, data nor analysis for his conclusions. Here, Dr. Stiroh has compared the evidentiary records with the evidence of Dey's actual pricing practices.

The Plaintiffs also engage in an evaluation of several of the facts upon which Dr. Stiroh bases her opinions. (See Plaintiffs' Memo at 3). In doing so, they improperly ask the Court to evaluate the factual underpinnings of selected parts of Dr. Stiroh's report. These types of issues are properly left for cross-examination. See *McGonigal*, 2009 WL 712345, at *5; see also *Taylor, Bean & Whitaker Mortgage Corp. v. GMAC Mortgage Corp.*, 2008 WL 3819752, at *5.

Finally, Plaintiffs argue that Dr. Stiroh's opinion on Dey's understanding of the prevailing industry practice is not relevant under the False Claims Act, stating that industry practice is not a defense under federal law. (Plaintiffs' Memo at 3). In support of their position, Plaintiffs cite to a banking case and a securities fraud case, neither of which support their position. In both *Vermilye & Co. v. Adams Express Co.*, 88 U.S. 138 (1874) and *S.E.C. v. U.S. Funding Corp.*, No. Civ. 02-2089(WJM), 2006 WL 995499 (D.N.J. Apr. 11, 2006), the defendants acknowledged the federal violations and all of the required elements were met, but the defendants unsuccessfully tried to argue that the violations were in accordance with industry

and generally not update it over time" (Stiroh Report at 16) does not contradict Dr. Bradford's opinions. Dr. Bradford also noted that "[f]or all three subject drugs, Dey set its AWP within 10% to 15% of the prevailing brand AWP when it entered. Once AWP is set for Dey's subject drugs, further adjustment essentially never occurs."

practice. Unlike the defendants in *Vermilye* and *U.S. Funding Corp.*, here, Defendants are not arguing that industry practice is a defense to a proven violation of the False Claims Act, but rather, that Dey's understanding of industry practice goes to the falsity and scienter elements of the False Claims Act, preventing the establishment of a violation of the Act.⁷ As discussed above, the relevant question in determining the knowledge or scienter element under the False Claims Act is whether Dey knew (or was reckless in not knowing) that published AWP's were supposed to reflect acquisition costs. *See, e.g., Farmer*, 523 F.3d at 338. Without a government issued definition of AWP, evidence that Dey understood the industry practice to be to set a generic AWP at 10 to 20% below the AWP of the brand, and Dey's subsequent pricing for the subject drugs confirms that Dey acted in accordance with this belief is relevant to Dey's scienter. Testimony regarding Dey's understanding of industry practice is also relevant to show that Dey did not act "recklessly." *Cf. United States ex rel. Cox v. Iowa Health Sys.*, 29 F. Supp. 2d 1022, 1025 (S.D. Iowa 1998) ("A standard billing practice within an industry could hardly be said to be false, when no controlling authority requires parties to submit claims" in a certain way); *see generally* 1 John T. Boese, *Civil False Claims and Qui Tam Actions* § 2.06[C][1], at 2-210.6 (3d ed. 2009).

(Bradford Report at ¶ 89). Any comments by Dr. Bradford relating to the practices of other manufacturers is a different and separate opinion than one focusing on Dey's understanding of industry practice.

⁷ Plaintiffs' reliance on *Barragan v. Tyson Foods, Inc.*, No. C06-4037-DEO, 2008 WL 1776439 (N.D. Iowa Apr. 17, 2008) is similarly inapplicable. In *Barragan*, the plaintiff claimed that the defendant employer had interfered with her rights under the Family Medical Leave Act by terminating her employment for excessive absenteeism. The court granted the defendant's motion to strike the plaintiff's expert testimony because it found the expert opinion regarding generally accepted HR practices to be irrelevant to any issue of the FMLA interference claim. The plaintiff's expert's opinion that defendants failed to follow generally accepted HR practices would only show that the defendants had violated the FMLA either inadvertently or intentionally. It is not relevant in an FMLA case whether, if the defendants violated the FMLA, they did so inadvertently or intentionally - they would be liable in either situation. Unlike *Barragan*, in FCA cases, courts have found the government knowledge inference to be relevant to two key elements of the FCA: the falsity of the claim and the defendant's state of mind (scienter).

C. DR. STIROH'S OPINIONS REGARDING ALTERNATIVE REIMBURSEMENT BASES ARE ADMISSIBLE

Despite Plaintiffs' arguments to the contrary, Dr. Stiroh's opinions that alternative reimbursement bases were available to Medicare are both relevant and helpful to the jury. (Plaintiffs' Memo at 10-11). Dr. Stiroh opines that:

the Government has access to a variety of pricing statistics, including AMPs, and now ASPs, that allow it to assess approximate acquisition costs. AWP was not the only publicly available reimbursement statistic. With respect to Dey, specifically, its WACs were reported to the same compendia as its AWP and were incorporated into the reimbursement practices of 10 state Medicaid agencies. FSS prices were also publicly available.

(Stiroh Report at 30). Dr. Stiroh also examines these available prices, which are contained in graphical format in her figures A through K to her report. It is important to note that Plaintiffs have not challenged these figures, or their accuracy in plotting the various pricing points depicted. In fact, Dr. Stiroh's charts are similar to certain charts set forth by Plaintiffs' expert, Mr. Platt.

With respect to the opinions regarding the alternative prices set forth in the text of her report, Dr. Stiroh is not, as Plaintiffs claim, inviting the jury to measure Dey's conduct against something other than the existing law. Rather, Dr. Stiroh's figures and opinions demonstrate the breadth of pricing information for Dey's drugs that was available in the economic marketplace. Plaintiffs incorrectly argue that the existence of alternative reimbursement bases is not relevant to whether Dey acted knowingly. (Plaintiffs' Memo at 11). These alternative prices and Dr. Stiroh's analysis and subsequent opinions are highly relevant to the pertinent question of whether Dey knew (or was reckless in not knowing) that published AWP were supposed to reflect acquisition costs. *See, e.g., Farmer*, 523 F.3d at 338. The availability of these alternative prices demonstrate that Dey was objectively reasonable in its treatment of AWP. Dey voluntarily

provided its AMPs, WACs, and other pricing points to the compendia and CMS. In fact, as stated by Dr. Stiroh:

CMS had direct information regarding Dey's average transaction prices. As a condition of participating in the Medicaid programs, Dey entered into a Rebate Agreement and reported its AMPs to CMS. CMS used this pricing information to calculate federal rebates for state Medicaid programs. Each state received a unit rebate amount for its purchases of Dey's Abbreviated New Drug Application ("ANDA") drugs calculated as a fixed share of the AMP (this share was 10 percent from 1991 to 1993 and 11 percent from 1994 to the present).

(Stiroh Report at 3). Dey sent its AMPs for the subject drugs to CMS quarterly throughout the entire time period. AMP is a pricing term that is defined. Therefore, it is not economically or objectively unreasonable for Dey to treat its AWP as a different type of pricing point than its quarterly average AMP prices.

D. DR. STIROH'S WAC OPINIONS, IF OFFERED AT TRIAL, ARE ADMISSIBLE

In her report, Dr. Stiroh examines Dey's WAC under a variety of tests in order to evaluate its economic function for Dey. As a threshold matter, Dey does not intend to present these opinions about WAC at trial unless Plaintiffs put these opinions at issue or otherwise make them relevant to the Medicare-only case that is scheduled for trial. Dr. Stiroh's expert report relates to both the Medicaid and Medicare programs, and her WAC opinion has particular relevance in the Medicaid context. However, it is possible that at trial, Plaintiffs will make arguments about Dey's WAC that would necessitate rebuttal by Dr. Stiroh. Therefore, the issue of relevancy of her WAC opinions is one that can and should be deferred until trial.

In addition to challenging the relevancy of Dr. Stiroh's WAC opinions, Plaintiffs also challenge them as unreliable on a record that is itself unreliable and verging on misleading. Plaintiffs rely on opinions offered after the close of expert discovery by Mr. Platt which use

Dey's internal financial accounting method to set up a false conflict between a proper WAC analysis and accounting for other purposes. Plaintiffs leave the mistaken impression that Dr. Stiroh's opinions that Dey's WAC is an economically meaningful number are premised solely on the calculations contained in her Exhibits 5 and 6. This is not the case. Dr. Stiroh has evaluated Dey's use of WAC in the economic context of its daily operations. Dr. Stiroh studied Dey's transactional data, Dey's invoices, and the testimony and documents produced by Dey and opines that:

Dey's WAC is an invoice price to wholesalers. Dey's WACs are undiscounted prices that appear on Dey's wholesalers' invoices. . . . Dey's WACs are meaningfully related to its average transaction prices. Discounts and rebates are proportionally tied to WAC. Dey regularly updates its reported WACs, keeping them consistent with underlying transaction price trends.

(Stiroh Report at 3). Elsewhere, Dr. Stiroh concludes from her comparison of Dey's WACs and AMPs that "Dey updates its WACs in a manner that directly reflects underlying pricing activity." (*Id.* at 17). These analyses form the basis for Dr. Stiroh's opinion that Dey's WAC is an economically meaningful figure, and are not challenged by Plaintiffs.

In addition to the above analyses, Dr. Stiroh also considers the charts attached as Exhibit 5 and Exhibit 6 to her expert report in her determination that Dey's WAC is economically meaningful. Exhibits 5 and 6 contain two analyses that examine two different points on the chain of distribution between Dey, the wholesaler, and the end customer. Exhibit 5 examines the invoice price of each of Dey's shipments to wholesalers that are either sold by the wholesaler to the wholesaler's own customers or distributed by the wholesaler to customers for which Dey has a negotiated contract price. Exhibit 5 "shows the distribution of the prices that appear on Dey's invoices to wholesalers relative to WAC. Approximately 90 percent of Dey's shipments to wholesalers are at WAC." (Stiroh Report at 17) (emphasis added). Exhibit 6, on the other hand,

examines Dey's direct sales to wholesalers, excluding indirect sales for which wholesalers act as intermediaries between Dey and Dey's contract customer. Therefore, because the focus is on a different part of the distribution chain, the total dollar amount is a smaller subset of the dollar amount depicted on Exhibit 5. "As can be seen from the table, more than 70 percent of Dey's sales are within 5 percent of its prevailing WAC price." (*Id.*). Dr. Stiroh concludes from these exhibits that "Plaintiffs and their experts argue that Dey's reported WACs are falsely inflated and are not an accurate reflection of actual prices paid in the market for Dey's products. In my opinion, that is incorrect." (*Id.*).

Dr. Stiroh's methodology and review of the Dey transaction data and subsequent analysis which forms the basis of her Exhibits 5 and 6 is transparent and replicable. Plaintiffs have the underlying data used in these calculations and Dr. Stiroh provided all of her back-up materials and programs so that Plaintiffs could replicate her process if they chose to do so. If Plaintiffs disagree with Dr. Stiroh's decisions and resulting conclusions, in the unlikely event that Dr. Stiroh presents these opinions in a Medicare trial, Plaintiffs will have ample opportunity to challenge her decisions on cross-examination. Disagreement with an expert's conclusions does not render them unreliable or inadmissible.

Plaintiffs also claim that Dr. Stiroh's opinions contradict prior holdings of the Court and Dey's own practice. With respect to prior holdings of the Court, those holdings were made in different cases and different contexts. The calculation of a wholesale acquisition cost has not been decided in the trial context, nor has a fact finder had the opportunity to evaluate evidence on how Dey invoices at WAC, how Dey's published WAC declines over time in relationship to actual acquisition costs, and how Dey makes sales to wholesalers and to customers that have contracts with Dey. The calculations or tests used in other cases do not render Dr. Stiroh's

opinions any more or less reliable. Dr. Stiroh set out to examine the facts of this particular case from her own economic viewpoint. With respect to Dey's own practices, Plaintiffs are comparing apples to oranges without any context. Such comparisons are completely inapposite and unsupported. Dr. Stiroh, as an economist, performed a calculation where she compared Dey's reported WAC to what she determined to be the equivalent of wholesale acquisition cost. In doing so, she examined transaction data of direct sales made by Dey to wholesalers, not Dey's internal accounting documents or PowerPoint slides. Such documents are irrelevant to Dr. Stiroh's examination of Dey's invoice price to wholesalers and the acquisition cost of wholesalers in the course of formulating her opinion on whether Dey's WAC was economically meaningful.⁸

CONCLUSION

For the reasons set forth herein, this Court should deny the Plaintiffs' Motion in Limine to Exclude Certain Testimony of Dr. Lauren J. Stiroh.

Dated: July 9, 2010

Respectfully Submitted,

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⁸ It should be noted that Dr. Stiroh's treatment of WAC is consistent with the federal definition of WAC adopted by the Medicare Modernization Act in 2003. This Medicare statute defines WAC as "the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data." 42 U.S.C. § 1395w-3a (c) (6) (B). Prior to the MMA, there was no federal definition of WAC.

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on July 9, 2010, a copy to LexisNexis File and Serve for posting and notification to all parties.

By: /s/ Sarah L. Reid
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